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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,894	11/30/2001	Michael Hutchinson	0922/63690	4202
7590	08/02/2005		EXAMINER SMITH, RUTH S	
Ivan S. Kavrukov Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,894

Applicant(s)

HUTCHINSON, MICHAEL

Examiner

Ruth S. Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### ***Drawings***

The drawings were received on June 20, 2005. These drawings are unacceptable. Figure 1 was properly labeled as "Prior art" but applicant failed to provide a label of "Replacement Sheet".

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

### **Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

### ***Claim Objections***

Claims 1-11 are objected to because of the following informalities: In claims 1,10, line 4, "signals" should be "signal". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 1-11, 13, 14, 16 and 17, the specification does not adequately describe how a white matter suppressed (WMS) signal of SNc tissue is used to produce resultant signals indicative of PD or PSP (it appears, rather that WMS of peduncular or crus cerebri regions are obtained). Regarding claims 10 and 11, the specification does not adequately disclose how information is combined from the GMS and WMS images to produce signals indicative of PSP. Regarding claims 12-14, the specification does not adequately disclose how the MRI images are combined to differentiate between PD and PSP. Regarding claims 15-17, the specification does not adequately describe how the MRI images are combined to identify PSP.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

Art Unit: 3737

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,9,15,16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gosche. Regarding claims 1, 9, 15 and 16 Gosche discloses a method for detecting a variety of neurological disorders (including Parkinson's) by obtaining volumetric measurements indicative of atrophy due to a pathological process (col. 8 lines 39-58, col. 9 line 66 - col. 10 line 18). Gosche further discloses obtaining a plurality of images and performing segmenting/thresholding (i.e., suppressing) to classify GM, WM, CSF, etc. (e.g., col. 9 lines 33-40). Gosche further discloses using different MRI parameters (col. 11 lines 51-64). Although Gosche does not explicitly address SNc tissue, the whole brain image data (including subcortical structures) of Gosche inherently includes this region (see e.g., fig. 2-8). Alternatively, it would have been obvious at the time the invention was made to a person of ordinary

skill in the art to specifically image the substantia nigra in the invention of Gosche when diagnosing a neurological disorder such as Parkinson's as is well known in the art (as per applicants' admission in article (1), p. 815 and article (2) p. 697 –698, incorporated by reference). In addition, PD inherently involves a loss from lateral to medial portions of the SNc (as evidenced in article (1) p. 817 and article (2) p. 698, incorporated by reference).

Claims 2-4, 10-13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosche. Regarding claims 2, 3, 14 and 17, Although Gosche discloses T1 imaging, inversion recovery (IR) pulse sequences are not explicitly addressed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use inversion recovery pulse sequences because Applicant has not disclosed that such sequences provide an advantage, are used for a particular purpose, or solve a stated problem (see e.g., 11 (0013)). One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the multispectral data set based on PD, T1, and T2 sequences of Gosche since both enable WM/GM delineation for detecting neurological atrophy indicative of Parkinson's disease. Regarding claim 4, although Gosche does not explicitly address obtaining a ratio image, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to take a ratio of the different images of Gosche to objectively quantify signals for subsequent comparison/analysis as is well known in the art (as per applicants' admission in article (1) p. 817, incorporated by reference). Regarding claims 10-13, although Gosche does not explicitly address detecting PSP, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect PSP because Applicant has not disclosed that such detection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the detection of PD as taught by Gosche because both are able to diagnose presence and

severity of a neurological disorder related to PD (see e.g., Gosche col. 8 lines 51-58 and col. 9 lines 20-26).

### ***Response to Arguments***

Applicant's arguments filed June 20, 2005 have been fully considered but they are not persuasive. Applicant's arguments regarding the prior art rejections do not appear to be directed to the claimed invention. Regarding the rejections under 35 USC, 112 first paragraph, essential subject matter cannot be incorporated by reference using non-patent publications. (Applicant's attention is invited to MPEP 608.01 (p)). It should be noted that claims 5-8 were inadvertently objected to in the previous office action. It is clear from the rejection of claims 1-17 under 35 USC 112, first paragraph that it was not intended for claims 5-8 to have been objected to.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

Art Unit: 3737

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', with a stylized, cursive script.

Ruth S. Smith  
Primary Examiner  
Art Unit 3737

RSS